

## EXPRESS MAIL LABEL NO. EV 334 000 351 US

<b>INFORMATION DISCLOSURE STATEMENT</b>  Address to: Mail Stop Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket	LIFE-090CON4
	First Named Inventor	SOPP, JOHN P.
	Application Number	To Be Assigned
	Confirmation No.	To Be Assigned
	Filing Date	Herewith
	Group Art Unit	To Be Assigned
	Examiner Name	To Be Assigned
	Title:	"BODY FLUID SAMPLER"

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. Copies of Form PTO-1449 and 892 listing the references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record.

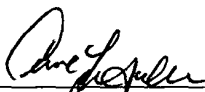
**All of the references identified herein were disclosed in parent application serial number 10/233,046, filed 08/30/2002 and as such, copies thereof are not included pursuant to the provisions of 37 CFR § 1.98(d).**

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of 35 U.S.C. §102.

As applicants have not yet received a first Action on the merits, no fee is believed to be required for filing this Disclosure Statement. If, however, the PTO finds that for some reason a fee is due, our Deposit Account No. 50-0815, Order No. LIFE-090CON4 may be charged thereon.

Respectfully submitted,  
 BOZICEVIC, FIELD & FRANCIS LLP

Date: 7/03/03

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FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number 9366.15USD1	Application Number 09/264,461
	Applicant: SOPP ET AL.	
	Filing Date: 03/03/1999	Group Art Unit: 3736

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	3,123,066	03/03/1964	Brumley			
	3,136,310	06/09/1964	Meltzer			
	3,208,452	09/28/1965	Stern			
	3,338,239	08/29/1967	Mausteller			
	3,958,560	05/25/1976	March			
	4,014,321	03/29/1977	March			
	4,195,641	04/01/1980	Johnes et al.			
	4,200,110	04/29/1980	Peterson et al.			
	4,407,290	10/04/1983	Wilber			
	BI 4,407,290	10/14/1986	Wilber			
	4,489,974	12/25/1984	Warhol			
	4,517,978	05/21/1985	Levin et al.			
	4,622,974	11/18/1986	Coleman et al.			

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	37 08 031 A1	11/12/1987	DE			X	
	0 160 768 A1	11/13/1985	EP				
	0 199 484 A2	10/29/1986	EP				
	0 212 906 A2	03/04/1987	EP				
	0 250 257 A1	12/23/1987	EP				
	0 453 283 A1	10/23/1991	EP				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Arnold, M. et al., "Determination of Physiological Levels of Glucose in an Aqueous Matrix with Digitally Filtered Fourier Transform Near-Infrared Spectra," <i>Anal. Chem.</i> , Vol. 62, pp. 1457-1464 (1990)
		Ash, S. et al., "Subcutaneous Capillary Filtrate Collector for Measurement of Blood Glucose," <i>ASAIO Journal</i> , Vol. 38, pp. M416-M420 (1992)
		Ash, S. et al., "A Subcutaneous Capillary Filtrate Collector for Measurement of Blood Chemistries," <i>ASAIO Journal</i> , Vol. 39, pp. M699-M705 (1993)
		Brace, R. et al., "Reevaluation of the Needle Method for Measuring Interstitial Fluid Pressure," <i>Am J. Physiol.</i> , Vol. 229, No. 3, pp. 603-607 (September 1975)
		DuPuy, N. et al., "Quantitative Analysis of Aqueous Solutions by FTIR Spectroscopy of Dry Extract", SPIE, Vol. 1575, 8th International Conference on Fourier Transform Spectroscopy, pp. 501-502 (1991)

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

<b>FORM 1449*</b> <b>INFORMATION DISCLOSURE STATEMENT</b>  <b>IN AN APPLICATION</b>  (Use several sheets if necessary)	Docket Number 9366,151/SDI	Application Number 09/264,461
	Applicant: SOPP ET AL.	
	Filing Date: 03/08/1999	Group Art Unit: 3736

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,637,403	01/20/1987	Garcia et al.			
	4,648,408	03/10/1987	Hutcheson et al.			
	4,655,225	04/07/1987	Dahne et al.			
	4,660,971	04/28/1987	Sage et al.			
	4,685,463	08/11/1987	Williams			
	4,703,756	11/03/1987	Gough et al.			
	4,704,029	11/03/1987	Van Heuvelen			
	4,730,622	03/15/1988	Cohen			
	4,750,830	06/14/1988	Lee			
	4,805,623	02/21/1989	Jobsis			
	4,873,993	10/17/1989	Meserol et al.			
	4,882,492	11/21/1989	Schlager			
	4,883,068	11/28/1989	Dechow			

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	0 582 226 A1	02/09/1994	EP			Abstract	
	2 033 575 A	05/21/1980	GB				
	WO 85/04089	09/26/1985	PCT				
	WO 88/00812	02/11/1988	PCT				
	WO 91/18548	12/12/1991	PCT				
	WO 95/10223	04/20/1995	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Gelman Science brochure, pg. 60 (1993) showing Nylaflo, Catalog P/N 32378.
		Gilanyi, M. et al., "Ion Concentrations in Subcutaneous Interstitial Fluid: Measured Versus Expected Values," <i>Am. J. Physiol.</i> (United States) Sept. 1988, 255 (3 Pt 2) pp. F513-F519
		Ginsberg, B. "An Overview of Minimally Invasive Technologies", <i>Clinical Chemistry</i> , Vol. 38, No. 9, pp. 1596-1600 (1992)
		"Glucose Sensors" and "Like An Injection" sections on page 26 of Diabetes Forecast, May, 1993
		Janle-Swain, E. et al., "Use of Capillary Filtrate Collector for Monitoring Glucose in Diabetics," <i>Trans. Am. Artif. Intern. Organs</i> , Vol. XXXIII, pp. 336-340 (1987)

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<b>FORM 1449*</b> <b>INFORMATION DISCLOSURE STATEMENT</b>  <b>IN AN APPLICATION</b>  (Use several sheets if necessary)	Docket Number 9366 15USD1	Application Number 09/264,461
	Applicant: SOPP ET AL.	
	Filing Date: 03/08/1999	Group Art Unit: 3736

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,901,728	02/20/1990	Hutchinson			
	4,953,552	09/04/1990	DeMarzo			
	4,954,318	09/04/1990	Yafuso et al.			
	4,960,467	10/02/1990	Peck			
	4,981,779	01/01/1991	Wagner			
	5,002,054	03/26/1991	Ash et al.			
	5,014,718	05/14/1991	Mitchen			
	5,026,388	06/25/1991	Ingalz			
	5,029,583	07/09/1991	Meserol et al.			
	5,035,704	07/30/1991	Lambert et al.			
	5,054,499	10/08/1991	Swierczek			
	5,066,859	11/19/1991	Karkar et al.			
	5,070,886	12/10/1991	Mitchen et al.			
	5,079,421	01/07/1992	Knudson et al.			
FOREIGN PATENT DOCUMENTS						
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
						YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
		Kayashima, S. et al., "New Noninvasive Transcutaneous Approach to Blood Glucose Monitoring: Successful Glucose Monitoring on Human 75 g OGTT with Novel Sampling Chamber," <i>IEEE Transactions on Biomedical Engineering</i> , Vol. 38, No. 8, pp. 752-757 (August 1991)				
		Kayashima S. et al., "Suction Effusion Fluid From Skin and Constituent Analysis: New Candidate for Interstitial Fluid," <i>Am J. Physiol</i> (United States) Nov. 1992, 263 (5 Pt 2), pp. H1623-H1627				
		Khstala, U., "Suction Blister Device for Separation of Viable Epidermis from Dermis," <i>Journal of Investigative Dermatology</i> , Vol. 50, No. 2, pp. 120-137 (1968)				
		Korthius, R. et al., "Method for Sampling Interstitial Fluid" from book entitled <i>Microcirculatory Technology</i> , edited by D. H. Baker et al., Academic Press, Chapter 21, pp. 326-327 (1986)				
		Mendelson, Y. et al., "Blood Glucose Measurement by Multiple Attenuated Total Reflection and Infrared Absorption Spectroscopy," <i>IEEE Transactions on Biomedical Engineering</i> , Vol. 37, No. 5, pp. 458-465 (May 1990)				

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<b>FORM 1449*</b> <b>INFORMATION DISCLOSURE STATEMENT</b>  <b>IN AN APPLICATION</b>  (Use several sheets if necessary)	Docket Number: 9366 15USD1	Application Number 09/264,461
	Applicant: SOPP ET AL.	
	Filing Date: 03/03/1999	Group Art Unit: 3736

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,115,133	05/19/1992	Knudson			
	5,146,091	09/08/1992	Knudson			
	5,179,951	01/19/1993	Knudson			
	5,201,324	04/13/1993	Swierczek			
	5,231,993	08/03/1993	Haber et al.			
	5,320,607	06/14/1994	Ishibashi			
	5,368,047	11/29/1994	Suzuki et al.			
	5,437,841	08/01/1995	Balmer			
	5,458,140	10/17/1995	Eppstein et al.			
	5,470,757	11/28/1995	Gagnon et al.			
	5,582,184	12/10/1996	Erickson et al.			
	5,682,233	10/28/1997	Brinda			
	5,746,217	05/05/1998	Erickson et al.			
	5,820,570	10/13/1998	Erickson et al.			
	5,879,310	03/09/1999	Sopp et al.			
	5,879,367	03/09/1999	Latterell et al.			

FOREIGN PATENT DOCUMENTS						
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
						YES NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Moatti-Sirat, D. et al., "Towards Continuous Glucose Monitoring: In Vivo Evaluation of Miniaturized Glucose Sensor Implanted for Several Days in Rat Subcutaneous Tissue", <i>Diabetologia</i> , Vol. 35, pp. 224-230 (1992)
		Petersen, L. et al., "Microdialysis of the Interstitial Water Space in Human Skin In Vivo: Quantitative Measurement of Cutaneous Glucose Concentrations," <i>J Invest Dermatol</i> , Vol. 99, No. 3, pp. 357-360 (September 1992)
		Turner, A. et al., "Diabetes Mellitus: Biosensors for Research and Management," <i>Biosensors</i> , Vol. 1, pp. 85-115 (1985)
		Wiig, H., "Evaluation of Methodologies for Measurement of Interstitial Fluid Pressure (Pi): Physiological Implications of Recent Pi Data," <i>Crit Rev Biomed Eng</i> , Vol. 18, No. 1, pp. 27-54 (1990)
		Wolfson, Jr., S. et al., "Glucose Concentration at Possible Sensor Tissue Implant Sites," <i>Diabetes</i> , Vol. 5, No. 3, pp. 162-165 (May-June 1982)

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<b>Notice of References Cited</b>	Applicant/Patent <b>Sopp et al.</b>	Application/Control No. <b>09/723,339</b>	
	Examiner <b>Michael P. Stafira</b>	Art Unit <b>2877</b>	Page 1 of 1

### U.S. PATENT DOCUMENTS

	Document Number Country Code-Number-Kind Code	Date MM-YYYY <sup>1</sup>	Name	Classification <sup>2</sup>	
A	5,879,310	3/1999	Sopp et al.	600	578
B					
C					
D					
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I					
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### FOREIGN PATENT DOCUMENTS

	Document Number Country Code-Number-Kind Code	Date MM-YYYY <sup>1</sup>	Country	Name	Classification <sup>2</sup>	
N						
O						
P						
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S						
T						


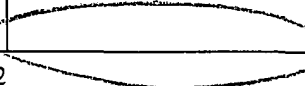
### NON-PATENT DOCUMENTS

	Include, as applicable: Author, Title, Date, Publisher, Edition or Volume, Pertinent Pages
U	
V	
W	
X	

\* A copy of this reference is not being furnished with this Office action. See MPEP § 707.05(a).

<sup>1</sup> Dates in MM-YYYY format are publication dates.

<sup>2</sup> Classifications may be U.S. or foreign.

CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this date.			
Typed or Printed Name	Cindy Kim Hoang		
Signature		Date	
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>  Address to: Commissioner for Patents Washington, D.C. 20231		Attorney Docket	LIFE-090DIV2
		First Named Inventor	SOPP, JOHN P.
		Application Number	10/233,046
		Filing Date	August 30, 2002
		Group Art Unit	2877
		Examiner Name	STAFIRA, MICHAEL PATRICK
		Title: "METHODS OF SAMPLING BODY FLUID"	

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. This is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in §1.491 in an international application or *after* the mailing date of the first Office Action on the merits, whichever event occurred last, but *before* the mailing date of either a final action under §1.113 or a notice of allowance under §1.311, whichever occurs first.

  X   All of the references identified herein are being submitted prior to the final determination on patentability by the Office.

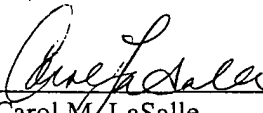
Applicants wish to bring to the Examiner's attention the following co-pending and commonly assigned applications (including at least a specification and corresponding drawings): U.S. Patent Application Serial No. 09,723,339, entitled "Body Fluid Sampler," filed November 27, 2000; U.S. Patent Application Serial No. 08,708,923, entitled "Needle Assembly for Fluid Sampler," filed September 6, 1996. Copies of pending applications are enclosed for the Examiner's review.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of 35 U.S.C. §102.

X Please charge the \$180.00 fee required by 37 C.F.R. §1.97(c) and set forth in 37 C.F.R. 1.17(p) and any additional fees which may be required by this paper or any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21, or to credit any overpayment, to Deposit Account No. 50-0815, order number LIFE-090DIV2.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: 4/3/03

By:   
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<b>Notice of References Cited</b>	Application/Control No. 10/233,046	Applicant(s)/Patent Under Reexamination SOPP ET AL.	
	Examiner Michael P. Stafira	Art Unit 2877	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,582,184 a1	12-1996	Erickson et al.	600/576
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
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